

November 27, 2002

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd.: Suite #300
Irvine, Ca 92612-2445

RIVERSIDE

3660 ARLINGTON AVENUE RIVERSIDE, CA 92506 (909) 683-6370 MQSA Facility Inspection Inspection ID: 1691100009

Facility: 7160 Brockton Avenue in Riverside, CA 92506

Dear Mr. Sawyer:

RIVERSIDE

6780 INDIANA AVENUE RIVERSIDE, CA 92506 (909) 683-6370 This letter is in response to the Warning Letter we received regarding our MQSA inspection on September 11, 2002.

RIVERSIDE

7150 BROCKTON AVENUE RIVERSIDE, CA 92506 (909) 683-6370

ARLINGTON

9041 MAGNOLIA AVENUE RIVERSIDE, CA 92503 (909) 352-6700

CANYON SPRINGS

6405 DAY STREET RIVERSIDE, CA 92507 (909) 697-5555

CORONA

830 MAGNOLIA AVENUE CORONA, CA 92879 (909) 683-6370

JURUPA VALLEY

6250 CLAY STREET RIVERSIDE, CA 92509 (909) 683-6370

SURGERY CENTER 7160 BROCKTON AVENUE RIVERSIDE, CA 92506

(909) 782-3801

Response to Level 2 Violations:

- Radiology Technologist [proper name redacted] has now met her CEU requirements- see attachment A. For the future a log has been setup for monthly monitoring on current CEU status for each Technologist. The lead Mammography Tech and Ancillary Supervisor will monitor for compliance. See attachment B.
- Medical Audit and Outcome Analysis for the whole facility has been completed-see attachment C. The technologists will review the Medical Audit and Outcome Analysis status monthly to ensure compliance. In the future the Medical Audit and Outcome Analysis will be done for the facility as a whole and as well for each individual radiologist annually.
- Infectious Control infectious control has been followed but there was no log showing compliance. Infectious Control log has been put in place – see attachment D & E.
- Interpreting Physician, [proper name redacted], M.D., has completed required CME. See attached letter from Riverside Radiology Medical Group for process of ensuring compliance of the completing and tracking of CME for interpreting physicians. Attachment F. If the Radiologist doesn't have his/her current 15 CME's within the three-year requirements, they will not be permitted to read mammography until he/she has CME units completed.
- Assessment Category- see attached memo to interpreting physicians regarding one final assessment category in each report. Attachment G.

As far as our repeat violations, it is the responsibility of Dr. [proper name redacted] as the supervising Radiologist to ensure compliance with MQSA. As for the violation in missed CEU's of the mammography technologist performing mammograms without her required CEU's, we miss read her documentation. The lead Mammography Technologist and Ancillary Supervisor will track the CEU's of all technologists on a monthly basis.

We at Riverside Medical Clinic have taken these violation very seriously, if you have any further questions please contact me at 909 782-3887.

Sincerely,

Kathy Thomas-Parsley Director of Ancillary Services